510(k) Summary

K091373

This summary of 510(k) safety and effectiveness is provided in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Date Prepared; March 30th, 2009

General Information

MAY 20 2009

Manufacturer Facility (Developer/manufacturer)
Siemens Medical Solutions USA, Inc.
20 Valley Stream Pkwy
Malvern, PA 19355
Establishment Registration Number: 3002329443

Contact Person
James E. Kuhn Jr.
Senior Regulatory Submissions Manager
Phone: (610) 448-3006 Fax: (610) 448-4274

Device Name and Classification

Trade Name:	*syngo™ TrueD Software*
Classification Name:	Picture Archiving and Communications System
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description and Intended Use

syngo TrueD is a medical diagnostic application for viewing, manipulation, 3D- visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering.

syngo TrueD enables visualization of information that would otherwise have to be visually compared disjointedly. *syngo* TrueD provides analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations.

syngo TrueD is designed to support the oncological workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of any such lesions. The application allows to store and export volume of interest (VOI) structures in DICOM RT format for use in radiation therapy planning systems.

syngo TrueD allows visualization and analysis of respiratory gated studies to support accurate delineation of the target or treatment volume over a defined phase of the respiratory cycle and thus provide information for radiation therapy planning.

Technological Characteristics

TrueD will be marketed as a software only solution for the end-user (with recommended hardware requirements) .It will be installed by Siemens service engineers. The TrueD described supports DICOM formatted images and information. It is based on the Windows XP operating system.

Safety Information

A summary of the software design description, hazard analysis, and technical and safety information can be found in the attached submission. The results of the hazard analysis, combined with the appropriate preventive measures taken indicate the device is of minor level of concern, as per *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices, May 2005*

The device has no patient contacting materials and is utilized only by trained professionals. The output of the device is evaluated by trained professionals allowing sufficient review for identification and intervention in the event of a malfunction. Device output and analysis is used to indicate the appropriateness of a referral. The device does not impact the quality or status of the original acquired data.

Substantial Equivalence:

The *syngo TrueD Software* is substantially equivalent, both in intended use and technically, to the following devices:

Predicate Device Name	*'DA Clearance Number*
TrueD	K071950
GE PET VCAR	K063324
MiMVista (Mim Contouring)	K071964
GE Advantage 4D Option	K032915
Siemens syngo Circulation	K063762

In summary, Siemens is of the opinion that the indicated change to the syngo TrueD software, as described within this submission does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

REV B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

Siemens Medical Solution USA, Inc.
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Rd.
NORTHBROOK IL 60062

Re: K091373
Trade/Device Name: Syngo™ TrueD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 28, 2009
Received: May 11, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

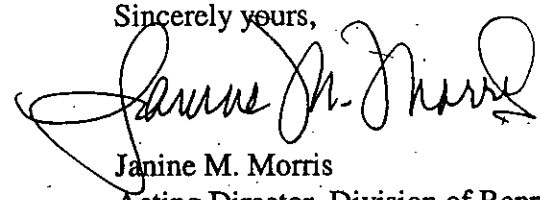
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not Known~~ K091373

Device Name: Syngo™ TrueD

Indications for Use:

syngo TrueD is a medical diagnostic application for viewing, manipulation, 3D- visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering.

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syngo TrueD allows visualization and analysis of respiratory gated studies to support accurate delineation of the target or treatment volume over a defined phase of the respiratory cycle and thus provide information for radiation therapy planning.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. *syngo* TrueD is a complement to these standard procedures.

Prescription Use (Part 21 CFR 801 Subpart D)	✓	AND / OR	Over-The-Counter-Use (Part 21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091373